

Application Ser. No. 10/501,110
Amendment and Response dated December 17, 2007
Reply to Office Action of July 19, 2007

Attorney Docket No. 61625(70232)

REMARKS

Claims 1-17 are pending in the application. Claim 1 is currently amended. Accordingly, claims 1-17 will remain pending in the application.

Claim 1 has been amended to claim more fully the recited subject matter and to make minor editorial changes. Support for the amendment to Claim 1 may be found in the specification as filed at least, for example, at page 5, lines 21-23 and Claim 1 as originally filed. No new matter has been added.

Amendment of the claims herein is not to be construed as acquiescence to any objections/rejections set forth in the instant Office Action and were done solely to expedite prosecution of the application. Applicants reserve the right to pursue the subject matter of the claims as originally filed in this or one or more subsequent patent applications.

Specification

Objection is made to the abstract of the disclosure as originally filed. In particular, the Office Action at page 2 indicates that "the abstract does not disclose that which is new in the art to which the invention pertains" and that because "the patent application is in the nature of an improvement to old processes or compositions, the abstract should include the technical disclosure of the improvement". Applicants respectfully disagree.

Applicants submit that the abstract fully complies with the requirements of 37 C.F.R. §1.72(b), which states:

"A brief abstract of the technical disclosure in the specification must commence on a separate sheet, preferably following the claims, under the heading "Abstract" or "Abstract of the Disclosure." The sheet or sheets presenting the abstract may not include other parts of the application or other material. The abstract in an application filed under 35 U.S.C. §111 may not exceed 150 words in length. The purpose of the abstract is to enable the United States Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure."

From a plain reading of 37 C.F.R. §1.72(b), the rule nowhere requires that an abstract include "that which is new in the art", as stated on page 2 of the Office Action

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of July 19, 2007. Importantly, 37 C.F.R. §1.72(b) requires that an abstract enable one "to determine quickly from a cursory inspection the nature and gist of the technical disclosure". Applicants respectfully submit that the abstract as filed does fully and fairly convey the nature and the gist of the technical disclosure. Moreover, 37 C.F.R. §1.72(b) contains no prohibition regarding purported merits or speculative applications of the invention, although Applicants further submit that the abstract as filed does not refer to purported merits or speculative applications of the invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection to the abstract.

Claim Rejections – 35 U.S.C. §112

Claims 1-11 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Applicants respectfully disagree and traverse the rejection.

The Examiner states that, in step (2) of claim 1, "immunogen denatured previously" lacks antecedent basis. However, step (2) of claim 1, as amended, recites "adding an antibody, wherein the antibody is raised against the water-sparingly-soluble/hardly extractable protein that is denatured previously..." The above amendment further clarifies this matter and obviates the rejection.

The Examiner further states that, in step (2) of claim 1, "the ionic surfactant used in step (1)" lacks antecedent basis. This is not understood because the term "ionic surfactant" is introduced in step (1).

The Examiner also states that, in step (2)(a), "the solution" lacks antecedent basis. The above amendment provides antecedent basis for "the solution" in step (1) and, thus, obviates the rejection.

Applicants respectfully submit that the claim 1, and claims 2-11 depending therefrom, fully comply with the requirements of 35 U.S.C. §112, second paragraph, and, therefore, respectfully request reconsideration and withdrawal of the rejection.

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Claim Rejections – 35 U.S.C. §102

Claims 1, 4-7 and 11-17 are rejected under 35 U.S.C. §102(b) as anticipated in view of U.S. Patent 4,658,022 to Knowles and Marchesi ("Knowles and Marchesi"). Applicants respectfully disagree and traverse the rejection.

In order to anticipate the invention as claimed, the cited referenced must teach each and every element of the claim. The presently claimed invention includes the steps of:

- (1) extracting and/or solubilizing a water-sparingly-soluble/hardly extractable protein in a sample with an aqueous solvent containing an ionic surfactant to provide a protein solution,
- (2) adding an antibody, wherein the antibody is raised against the water-sparingly-soluble/hardly extractable protein that is denatured previously with the ionic surfactant used in step (1), to...

Thus, the present invention includes using an antibody raised against the extractable protein, itself, denatured with the ionic surfactant used in step (1). In contrast, Knowles and Marchesi fail to teach or suggest raising the antibody by using the extracted and denatured protein as an immunogen. Instead, Knowles and Marchesi teach preparing antibodies against a synthetically derived immunogen [col. 3, lines 50-56; col. 7, lines 9-30]. Although Knowles and Marchesi describe denaturing the extracted protein before adding the antibody when conducting the immunoassay, they neither teach nor suggest using the extracted protein as extracted and denatured to raise the antibody.

Because Knowles and Marchesi does not teach or suggest the element of raising the antibody by using the extractable protein, itself, denatured with the ionic surfactant used in step (1), the patent does not anticipate the presently claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of Claim 1, and Claims 4-7 and 11-17 depending therefrom, under 35 U.S.C. §102(b).

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Claim Rejections – 35 U.S.C. §103

Claims 2, 3, and 8-10 are rejected under 35 U.S.C. §103(a) as allegedly obvious over Knowles and Marchesi in view of Powell, CURRENT PROTOCOLS IN MOLECULAR BIOLOGY, Unit 17.14A, John Wiley & sons, Inc. (1995) ("Powell"). Applicants specifically disagree and traverse the rejection.

Applicants note that Claim 1 is not subject to the rejection under 35 U.S.C. §103(a) over Knowles and Marchesi in view of Powell. It is axiomatic that if an independent claim is not obvious over a cited combination of references, then dependent claims, which, by definition, contain the limitation(s) of the independent claim from which they directly or indirectly depend (37 C.F.R. §1.75(c)), are also not obvious. Claims 2, 3, and 8-10 depend directly or indirectly from Claim 1. Accordingly, it follows that Claims 2, 3, and 8-10 are not obvious because the rejected dependent claims all contain limitations to Claim 1, and Claim 1 has not been rejected as obvious in view of the references cited.

Nevertheless, responding to the Examiner's allegation that Claims 2, 3, and 8-10 are obvious in view of the references cited, Applicants respectfully disagree. In order to make out a prima facie showing of obviousness, the Examiner must establish that there is some motivation in one or the other of the cited references or in the state of the art at the time the invention was made to combine the references, the combination of references must teach or suggest each and every element of the claimed invention, and there must be some reasonable expectation of success in making and using the invention.

As acknowledged by the Examiner on page 4 of the Office Action, Knowles and Marchesi do not teach "particular sodium dodecyl sulfate (SDS) concentrations and 2-mercaptoethanol concentration in the 'aqueous solvent' or 'a boiling step.'" The Examiner has further cited Powell as an alleged remedy for this deficiency of Knowles and Marchesi.

However, the claims as currently amended recite "an antibody, wherein the antibody is raised against the water-sparingly-soluble/hardly extractable protein that is denatured." As indicated in the above response to the rejection under 35 U.S.C. §102(b), Knowles and Marchesi do not teach or suggest using an antibody raised against the extracted and denatured immunogen. Likewise, Powell also does not

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teach or suggest using an antibody raised against the extracted and denatured immunogen and, therefore, does not make up for the deficiencies in Knowles and Marchesi.

Thus, there is nothing in either of the cited references or in the state of the art at the time the invention was made that provides one of ordinary skill in the art with motivation to combine the references in the manner proffered by the Examiner. Assuming for the sake of argument that there were such motivation, the combination does not teach or suggest each and every element of the claimed invention because neither reference teaches or suggests using an antibody raised against the extracted and denatured immunogen. Therefore, because the cited combination of references does not put one of ordinary skill in the art in possession of the claimed invention, one of ordinary skill in the art would not have a reasonable expectation of success in making and using the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 2, 3, and 8-10 under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing amendments and arguments, Applicants respectfully request reconsideration and withdrawal of all pending objections/rejections and allowance of the applications with claims 1-17 presented herein. If a telephone call with Applicants' representative would be helpful in expediting prosecution of the application, Applicants invite the Examiner to contact the undersigned at the telephone number shown below.

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Respectfully submitted,

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